

REMARKS

Claims 1-10, 12-19, 24-54 are pending in the present application. Claims 27-40 and 50-54 are withdrawn from consideration. Claims 1-10, 12-19, 24-26 and 41-49 are being prosecuted, and each claim has been amended. Reconsideration of the patentability of the pending claims in view of the amendments and the following remarks is respectfully requested. English language translations of the German language priority applications are enclosed.

Each claim has been amended to more clearly state that the claimed invention is a plurality of pharmaceutical formulations which exhibit release of the active compounds in an invariant and independent manner when compared to one another.

Claim Objection

The Examiner has objected to claim 1 for the use of open language in a Markush group. Each of the pending claims has been reviewed with regard to the Examiner's objection, and it is submitted that proper Markush group claim language has been inserted wherever appropriate, including in claim 1. Withdrawal of the Examiner's objection is respectfully requested.

Claim Rejections - 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 1 and 41 under 35 U.S.C. § 112, first paragraph, regarding the claiming of derivatives. Without prejudice towards pursuing such claims in the future, applicants have deleted the language regarding derivatives from claims 1 and 41. Withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1, 4 and 41 under 35 U.S.C. § 112, second paragraph, regarding the claiming of derivatives and the absence of relevant amounts. Without prejudice towards pursuing such claims in the future, applicants have deleted the language regarding derivatives and relevant amounts from claims 1, 4 and 41. Withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Statement of Obligation of Assignment to The Same Person Under 35 U.S.C. § 103(c)

The Examiner has rejected claims 1-10, 12-19, 24-26 and 41-49 under 35 U.S.C. § 103(a) as being unpatentable over European Patent Application No. EP 0 699 436 B1 to Miller et al. (“Miller”) in view of U.S. Patent No. 7,332,182 to Sackler (“Sackler”) and U.S. Patent No. 6,306,438 to Oshlack et al. (“Oshlack”).

The rejection is respectfully traversed.

It is respectfully submitted that the Sackler patent is not available as a reference under 35 U.S.C. § 103(a). The Sackler patent purportedly qualifies as “prior art” only under 35 U.S.C. § 102(e). However, pursuant to 35 U.S.C. § 103(c),

[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The Manual of Patent Examining Procedure states that:

The following statement is sufficient evidence to establish common ownership of, or an obligation for assignment to, the same person(s) or organizations(s):

Applications and references (whether patents, patent applications, patent application publications, etc.) will be considered by the examiner to be owned by, or subject to an obligation of assignment to the same person, at the time the invention was made, if the applicant(s) or an attorney or agent of record makes a statement to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person.

See MPEP, section 706.02(l)(2).

Applicants hereby respectfully state that the present application and the Sackler patent were, at the time the present invention was made, subject to an obligation of assignment to the same person.

In support of applicants’ statement under 35 U.S.C. § 103(c), submitted herewith are the following documents:

- A) the employment agreement of inventor Bianca Brogmann (Exhibit A);
- B) the employment agreement of inventor Silke Muehlau (Exhibit B);
- C) the employment agreement of inventor Christof Spitzley (Exhibit C);
- D) the Notice of Recordation of Assignment regarding the Sackler patent (Exhibit D);
- E) the Assignment regarding the Sackler patent (Exhibit E);
- F) the Notice of Recordation of assignment of the present invention by the inventors (Exhibit F); and
- G) the Assignment of the present invention by the inventors (Exhibit G).

Withdrawal of the rejection is therefore respectfully requested.

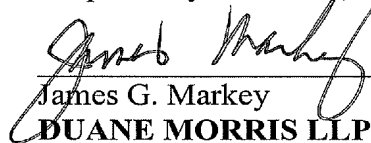
Conclusion

Reconsideration of the patentability of claims 1-10, 12-19, 24-26 and 41-49 in view of the above amendments and remarks is requested. It is respectfully submitted that all claims are in condition for allowance, early notification of which is requested.

It is believed that no fees beyond those for the Petition for Extension of Time and the Supplemental Information Disclosure Statement are required for the filing of this response. However, the Commissioner is hereby authorized to charge any required fees to Duane Morris LLP Deposit Account No. 04-1679.

Date: November 9, 2009

Respectfully submitted,


James G. Markey
DUANE MORRIS LLP

1540 Broadway
New York, New York 10036
Tel: (212) 692-1000
Fax: (212) 692-1020

31,636
(Reg. No.)

Enclosures

8 December 1995

Dear Dr. Brögmann,

We are delighted to inform you that the trial period laid down in your Employment Contract for the recognition of your achievements has come to an end as of 16 January 1996. As of 17 January 1996 your employment is not subject to any definite term.

We trust you will continue to pursue your activities with pleasure and enthusiasm in the future as well, so that we look forward to success in working together.

This letter has been written in duplicate and hence becomes a part of your Employment contract. Kindly confirm receipt on the copy.

Yours sincerely,

Mundipharma GmbH

W. Wimmer

Brögmann

Employment Contract

between

Mundipharma GmbH
Mundipharma Strasse 2
65549 Limburg/Lahn

-referred to hereinafter as "Company"-

and

Dr. Bianca Brögmann
Wilhelminenstr. 6
64283 Darmstadt

-referred to hereinafter as "Employee"-

Article 1 Activities and Area of Assignment

- (1) As with effect of 17 July 1995, the Employee will be recruited as Head of R & D in the Company's in-house division R & D.
- (2) The Company will retain the right to allocate the Employee to another comparable area of engagement in accordance with her previous training and her abilities without amending her remuneration.

Article 2 Working Hours

- (1) Regular working hours will amount to 37.5 hours per week.
- (2) Should it be necessary for company-related reasons, the Employee undertakes to work overtime to a reasonable degree.

Article 3 Ancillary Activities

- (1) The Employee undertakes to devote her full working hours and capacity to the business operations of the Company. All other activities for which payment is made and those that are generally subject to a claim to payment, including all form of part-time employment, will be subject to the explicit prior consent of the Company.
- (2) Academic and literary activities will be permitted providing these do not have a detrimental affect on the working capacity of the Employee and do not thus culminate in classified information of the Company being passed on to its disadvantage.

REDACTED

**Article 4
Remuneration**

- (1) The Employee will receive a monthly gross salary of _____ (in words: _____). After a successfully completed trial period, the monthly gross salary will be increased to _____ (in words: _____).
- (2) Furthermore subject to the following criteria, the Employee will be entitled to payment of a 13th (thirteenth) month's salary, which will become due for payment in November of each year.

The amount will be paid in full to the Employee providing at the time payment is due she has been employed with the company for at least 12 (twelve) months. If her period of service with the company is less than 12 (twelve) months on said due date, she will be entitled to payment of one twelfth of the full amount of bonus for each completed month of employment. This will also apply if she joins the Company after the 30 September.

The Company will be entitled to offset any justified claims to repayment against any claims of the Employee to payment either in arrears or due after the service of notice, taking due account of the provisions governing protection from attachment.

- (3) Upon payment of the above amounts, all activities of the Employee subject to the present Employment Contract will be deemed paid for. Most specifically, the Employee will not be entitled to extra payment for overtime.
- (4) Any assignment of salary claims to third parties will only be permissible subject to the consent of the Company.

**Article 5
Additional Benefits**

- (1) Travel costs and other disbursements incurred by the Employee in acting for the Company will be refunded to her subject to the valid Travel Costs Regulations for In-House Employees and subject to the fiscal guidelines applicable in Germany.
- (2) Upon application as defined by the *Vermögensbildungsgesetz* [Capital Formation Act], the Employee will receive a benefit amounting to _____ per month. The Employee undertakes to provide the Company in good time with a copy of the relevant contract. Part-time employees will be entitled to a proportional benefit contributing to capital formation, depending on the duration of their contractual working hours. The claim to the benefit will be first generated upon the beginning of the 7th (seventh) calendar month of an uninterrupted period of employment with the Company.

If, directly prior to joining the Company, the Employee was engaged in the chemical industry and already benefited from the contributory payments from her former employer, the beginning of the fourth calendar month will take the place of the

beginning of the 7th (seventh) calendar month. Upon leaving the Company, the claim to these benefits will extinguish with the last full calendar month of employment.

- (3) The Employee may apply for incorporation into the Company pension fund as of 01.07.1996.

Article 6 Inability to Work

- (1) The Employee will inform the Company immediately of any absence and its likely duration. Upon being requested, she will inform the Company of the reasons for being unable to work.
- (2) In cases of sickness-related working incapacity, the Employee will provide the Company with a medical certificate regarding her working incapacity and its likely duration before the expiry of the 3rd calendar day. Should the incapacity persist for longer than specified in the medical certificate, the Employee will present another medical certificate to the Company inside three days after expiry of the interval of sickness specified in the (preceding) medical certificate.

Article 7 Vacation

REDACTED

- (1) The Employee will be entitled to 30 workdays' annual leave.
- (2) The vacation will be taken in coordination with the Company, although account will be taken of the personal wishes of the Employee.
- (3) The Company will pay the Employee a holiday allowance of _____ gross per day of vacation.

Article 8 Non-disclosure

- (1) The Employee undertakes not to pass on to third parties or to use for her own personal advantage any confidential information confided in her or of which she is otherwise aware, or any technical or business-related information relating to the Company or to one of its Group companies. In particular no information relating to the organization of business, relations with customers or suppliers or other know-how of the Company will be passed on. The present undertaking will not extinguish upon termination of employment, but will continue to apply beyond that date.
- (2) Business documents of every nature, including private records on issues and activities of the Company will be kept carefully and may only be used for business-related purposes. It will be permitted to make copies or take excerpts and to copy drawings, calculations, statistics, etc. and all other business documents exclusively for Company-related purposes.
- (3) After termination of the present Employment Contract, the Employee will surrender without being requested all business documents in her possession and to which the Company is entitled – even her own records – as well as other items to which the Company is entitled. Under no circumstances will the Employee have any right of retention.

Article 9 Inventions

- (1) In terms of Employee inventions, the regulations of the Employee Invention Act will apply as well as the associate guidelines.

Article 10 Duration and Termination of Employment

- (1) The present Employment Contract takes effect as from 17 July 1995 and will be of an indefinite term. The first 6 (six) months will be deemed a trial period. During this interval, one month's notice to the end of a month may be served by each of the Parties to the Contract. After the trial period, the two Parties may serve three months' notice to the end of a calendar quarter. Should the period of notice lengthen by law for the Company, the lengthened period of notice will also apply for the Employee. Irrespective thereof, employment will automatically terminate upon the expiry of the month in which the Employee becomes 65 years of age.
- (2) In the event notice is served on employment, the Company will be entitled to discharge the Employee from her working obligations, whilst continuing to pay her contractual remuneration giving due consideration to her remaining claim to annual leave.
- (3) In particular the Company will be entitled to serve extraordinary notice, if the Employee provides inaccurate information in her activity reports or in her travel cost statements.
- (4) Notice will be served in the written form.

Article 11 Medical Examination

The Employee agrees to a medical examination upon recruitment. The costs thus incurred will be borne by the Company.

Article 12 Police Clearance Certificate

Recruitment will require a *Führungszeugnis* [police clearance certificate]. The costs thus incurred will be borne by the Company.

Article 13

Personal data of the employee will be electronically saved.

Article 14 Concluding Provisions

- (1) The present Employment Contract embodies the full agreement between the Parties. The Parties agree that any written or verbal agreements prior to the present Employment Contract will be replaced by the present Contract and will no longer be legally operative.

- (2) Amendments or additions to the present Employment Contract will be subject to the written form to be legally operative.
- (3) Should any one provision of the present Employment Contract be or become legally invalid, the legal validity of the remaining provisions will not be affected hereby. The Parties undertake to replace the legally invalid provisions by those which come as close as possible to the business-related purpose of said provisions.

Limburg/Lahn 28 March 1995

Mundipharma GmbH

Wimmer

Brögmann

21 September 2000

Dear Dr. Decker,

The term of your Employment Contract of 27 April 1998 is restricted up until 30.06.2001.

On the grounds of your performance, however, with immediate effect we are now amending the restricted term into an unrestricted term of employment.

All other terms of your contract remain unaltered.

This letter has been written in duplicate and hence becomes a part of your Employment Contract. Please return one copy to us signed by you.

We wish you continued pleasure and success in your activities.

Yours sincerely,

Dr. W. Fleischer
Area Manager

M. Schöne
Head of Human Resources

Dr. Silke Decker

Employment Contract of Restricted Term

between

Mundipharma GmbH
Mundipharma Strasse 2
65549 Limburg/Lahn

-referred to hereinafter as "Company"-

and

Dr. Silke Decker
Am Happach 46
97218 Gerbrunn

-referred to hereinafter as "Employee"-

Article 1 Activities and Area of Assignment

- (1) As with effect of 1 July 1998 until 30 June 2001 the Employee will be recruited as Laboratory Manager for Pharmaceutical Development in the Company's in-house division of "R & D".
- (2) The Company will retain the right to allocate the Employee to another comparable area of engagement in accordance with her previous training and her abilities without amending her remuneration.

Article 2 Working Hours

- (1) Regular working hours will amount to 37.5 hours per week.
- (2) Should it be necessary for company-related reasons, the Employee undertakes to work overtime to a reasonable degree.

Article 3 Ancillary Activities

- (1) The Employee undertakes to devote her full working hours and capacity to the operations of the Company. All other activities for which payment is made and those that are generally subject to a claim to payment, including all form of part-time employment, will be subject to the explicit prior consent of the Company.
- (2) Academic and literary activities will be permitted providing these do not have a detrimental affect on the working capacity of the Employee and do not thus culminate in confidential information of the Company being passed on to its disadvantage.

REDACTED

Article 4 Remuneration

- (1) In return for her deployment, the Employee will receive a monthly gross salary of
in words: ---) /AT.
- (2) Furthermore subject to the following criteria, the Employee will be entitled to payment of a Christmas bonus to the order of one month's salary, which will become due for payment in November of each year.

The Christmas bonus will be paid in full to the Employee providing at the time payment is due she has been employed with the company for at least 12 (twelve) months. If her period of service with the company is less than 12 (twelve) months on said due date, she will be entitled to payment of one twelfth of the full amount of bonus for each completed month of employment. This will also apply if she joins the Company after the 30 September.

The Employee undertakes to pay back the bonus if, on the grounds of notice served by herself or by the Company or because employment is cancelled for reasons that are not operational, she leaves employment by 31 March. In this case the Company will be entitled to offset the claim to repayment against any claims of the Employee to payment either in arrears or due after the service of notice, taking due account of the provisions governing protection from attachment.

- (3) Upon payment of the above amounts, all activities of the Employee subject to the present Employment Contract will be deemed paid for. Most specifically, the Employee will not be entitled to extra payment for overtime.
- (4) Any assignment of salary claims to third parties will only be permissible subject to the consent of the Company.

Article 5 Additional Benefits

- (1) Travel costs and other disbursements incurred by the Employee in acting for the Company will be refunded to her subject to the valid Travel Costs Regulations for In-House Employees and subject to the fiscal guidelines applicable in Germany.
- (2) Upon application as defined by the *Vermögensbildungsgesetz* [Capital Formation Act], the Employee will receive a benefit amounting to --- per month. The Employee undertakes to provide the Company in good time with a copy of the relevant contract. Part-time employees will be entitled to a proportional benefit contributing to capital formation, depending on the duration of their contractual working hours. The claim to the benefit will be first generated upon the beginning of the 7th (seventh) calendar month of an uninterrupted period of employment with the Company.

If, directly prior to joining the Company, the Employee was engaged in the chemical industry and already benefited from the contributory payments from her former employer, the beginning of the 4th (fourth) calendar month will take the place of the

beginning of the 7th (seventh) calendar month. Upon leaving the Company, the claim to these benefits will extinguish with the last full calendar month of employment.

- (3) Should the Employee be provided with a company car, the Company and the Employee will enter into a separate written agreement in respect thereof.

Article 6 Inability to Work

- (1) The Employee will inform the Company immediately of any absence and its likely duration. Upon being requested, she will inform the Company of the reasons for being unable to work.
- (2) In cases of sickness-related working incapacity, the Employee will immediately inform her Manager or the Personnel Department accordingly. In the case of sickness lasting for more than three workdays, a medical certificate relating to the given working incapacity and the likely duration thereof must be received by the Human Resources Department on the following workday at the latest. Subsequent certificates will be sent immediately to the Human Resources Department. However the employer will be entitled to call for a medical certificate at an earlier date.

Article 7 Vacation

REDACTED

- (1) The Employee will be entitled to 30 workdays' annual leave.
- (2) The vacation will be taken in coordination with the Company, although account will be taken of the personal wishes of the Employee.
- (3) The Company will pay the Employee a holiday allowance of : - gross per day of vacation.

Article 8 Non-disclosure

- (1) The Employee undertakes not to pass on to third parties or to use for her own personal advantage any confidential information confided in her or of which she is otherwise aware, or any technical or business-related information relating to the Company or to one of its Group companies. In particular no information relating to the organization of business, relations with customers or suppliers or other know-how of the Company will be passed on. The present undertaking will not extinguish upon termination of employment, but will continue to apply beyond that date.
- (2) Business documents of every nature, including private records on issues and activities of the Company will be kept carefully and may only be used for business-related purposes. It will be permitted to make copies or take excerpts and to copy drawings, calculations, statistics, etc. and all other business documents exclusively for Company-related purposes.
- (3) After termination of the present Employment Contract, the Employee will surrender without being requested all business documents in his possession and to which the Company is entitled – even his own records – as well as other items to which the

Company is entitled. Under no circumstances will the Employee have any right of retention.

Article 9 Inventions

- (1) In terms of Employee inventions, the regulations of the Employee Invention Act will apply as well as the associate guidelines.

Article 10 Duration and Termination of Employment

- (1) The present Employment Contract takes effect as from 1 July 1998 and will terminate on 30 June 2001 without being subject to notice. The first 6 (six) months will be deemed a trial period. During this interval, one month's notice to the end of a month may be served by each of the Parties to the Contract. After the trial period, the two Parties may serve six weeks' notice to the end of a calendar quarter. Should the period of notice lengthen by law for the Company, the lengthened period of notice will also apply for the Employee.

The present Employment Contract is of a restricted term since the position entails deputizing for an employee who will be taking childcare leave.

- (2) In the event notice is served on employment, the Company will be entitled to discharge the Employee from her working obligations, whilst continuing to pay her contractual remuneration giving due consideration to her remaining claim to annual leave.
- (3) In particular the Company will be entitled to serve extraordinary notice, if the Employee provides inaccurate information in her activity reports or in her travel cost statements.
- (4) Notice will be served in the written form.

Article 11 Medical Examination

The Employee agrees to a medical examination upon recruitment. The costs thus incurred will be borne by the Company.

Article 12 Police Clearance Certificate

Recruitment will require a *Führungszeugnis* [police clearance certificate]. The costs thus incurred will be borne by the Company.

Article 13

Personal data of the employee will be electronically saved.

Article 14
Concluding Provisions

- (1) The present Employment Contract embodies the full agreement between the Parties. The Parties agree that any written or verbal agreements prior to the present Employment Contract will be replaced by the present Contract and will no longer be legally operative.
- (2) Amendments or additions to the present Employment Contract will be subject to the written form to be legally operative.
- (3) Should any one provision of the present Employment Contract be or become legally invalid, the legal validity of the remaining provisions will not be affected hereby. The Parties undertake to replace the legally invalid provisions by those which come as close as possible to the business-related purpose of said provisions.

Limburg/Lahn 29 November 1996

Mundipharma GmbH

Walter Wimmer
Manager

M. Schöne
Head Human Resources

Dr. Silke Decker

Employment Contract

between

Mundipharma GmbH
Mundipharma Strasse 2
65549 Limburg/Lahn

-referred to hereinafter as "Company"-

and

Mr. Christof Spitzley
Ringstr. 7a
65627 Elbtal-Heuchelheim

-referred to hereinafter as "Employee"-

Article 1 Activities and Area of Assignment

- (1) As with effect of 1 February 1997 or earlier, the Employee will be recruited as chemical laboratory technician in the Company's in-house division of "Research and Development /Pharmaceutical Development".
- (2) The Company will retain the right to allocate the Employee to another comparable area of engagement in accordance with his previous training and his abilities without amending his remuneration.

Article 2 Working Hours

- (1) Regular working hours will amount to 37.5 hours per week.
- (2) Should it be necessary for company-related reasons, the Employee undertakes to work overtime to a reasonable degree.

Article 3 Ancillary Activities

- (1) The Employee undertakes to devote his full working hours and capacity to the operations of the Company. All other activities for which payment is made and those that are generally subject to a claim to payment, including all form of part-time employment, will be subject to the explicit prior consent of the Company.
- (2) Academic and literary activities will be permitted providing these do not have a detrimental affect on the working capacity of the Employee and do not thus culminate in classified information of the Company being passed on to its disadvantage.

REDACTED

Article 4 Remuneration

- (1) The Employee will receive a monthly gross salary of _____ (in words: _____)
- (2) Furthermore subject to the following criteria, the Employee will be entitled to payment of a Christmas bonus to the order of one month's salary, which will become due for payment in November of each year.

The Christmas bonus will be paid in full to the Employee providing at the time payment is due he has been employed with the company for at least 12 (twelve) months. If his period of service with the company is less than 12 (twelve) months on said due date, he will be entitled to payment of one twelfth of the full amount of the bonus for each completed month of employment. This will also apply if he joins the Company after the 30 September.

The Employee undertakes to pay back the bonus if, on the grounds of notice served by himself or by the Company or because employment is cancelled for reasons that are not operational, he leaves employment by 31 March. In this case the Company will be entitled to offset the claim to repayment against any claims of the Employee to payment either in arrears or due after the service of notice, taking due account of the provisions governing protection from attachment.

- (3) Upon payment of the above amounts, all activities of the Employee subject to the present Employment Contract will be deemed paid for. Most specifically, the Employee will not be entitled to extra payment for overtime.
- (4) Any assignment of salary claims to third parties will only be permissible subject to the consent of the Company.

Article 5 Additional Benefits

- (1) Travel costs and other disbursements incurred by the Employee in acting for the Company will be refunded to him subject to the valid Travel Costs Regulations for In-House Employees and subject to the fiscal guidelines applicable in Germany.
- (2) Upon application as defined by the *Vermögensbildungsgesetz* [Capital Formation Act], the Employee will receive a benefit amounting to _____ per month. The Employee undertakes to provide the Company in good time with a copy of the relevant contract. Part-time employees will be entitled to a proportional benefit contributing to capital formation, depending on the duration of their contractual working hours. The claim to the benefit will be first generated upon the beginning of the 4th (fourth) calendar month of an uninterrupted period of employment with the Company.

If, directly prior to joining the Company, the Employee was engaged in the chemical industry and already benefited from the contributory payments from his former employer, the beginning of the 4th (fourth) calendar month will take the place of the beginning of the 7th (seventh) calendar month. Upon leaving the Company, the claim to these benefits will extinguish with the last full calendar month of employment.

- (3) The Employee may apply for incorporation into the Company pension fund as of 01.07.1999.

Article 6 Inability to Work

- (1) The Employee will inform the Company immediately of any absence and its likely duration. Upon being requested, he will inform the Company of the reasons for being unable to work.
- (2) In cases of sickness-related working incapacity, the Employee will provide the Company with a medical certificate regarding his working incapacity and its likely duration before the expiry of the 3rd calendar day. Should the incapacity persist for longer than specified in the medical certificate, the Employee will present another medical certificate to the Company inside three days after expiry of the interval of sickness specified in the (preceding) medical certificate.

Article 7 Vacation

REDACTED

- (1) The Employee will be entitled to 30 workdays' annual leave.
- (2) The vacation will be taken in coordination with the Company, although account will be taken of the personal wishes of the Employee.
- (3) The Company will pay the Employee a holiday allowance of _____ gross per day of vacation.

Article 8 Non-disclosure

- (1) The Employee undertakes not to pass on to third parties or to use for his own personal advantage any confidential information confided in him or of which he is otherwise aware, or any technical or business-related information relating to the Company or to one of its Group companies. In particular no information relating to the organization of business, relations with customers or suppliers or other know-how of the Company will be passed on. The present undertaking will not extinguish upon termination of employment, but will continue to apply beyond that date.
- (2) Business documents of every nature, including private records on issues and activities of the Company will be kept carefully and may only be used for business-related purposes. It will be permitted to make copies or take excerpts and to copy drawings, calculations, statistics, etc. and all other business documents exclusively for Company-related purposes.
- (3) After termination of the present Employment Contract, the Employee will surrender without being requested all business documents in his possession and to which the Company is entitled – even his own records – as well as other items to which the Company is entitled. Under no circumstances will the Employee have any right of retention.

Article 9 Inventions

- (1) In terms of Employee inventions, the regulations of the Employee Invention Act will apply as well as the associate guidelines.

Article 10 Duration and Termination of Employment

- (1) The present Employment Contract takes effect as from 1 February 1997 or earlier and will be of an indefinite term. The first 6 (six) months will be deemed a trial period. During this interval, one month's notice to the end of a month may be served by each of the Parties to the contract. After the trial period, the two Parties may serve six months' notice to the end of a calendar quarter. Should the period of notice lengthen by law for the Company, the lengthened period of notice will also apply for the Employee. Irrespective thereof, employment will automatically terminate upon the expiry of the month in which the Employee becomes 65 years of age.
- (2) In the event notice is served on employment, the Company will be entitled to discharge the Employee from his working obligations, whilst continuing to pay his contractual remuneration giving due consideration to his remaining claim to annual leave.
- (3) In particular the Company will be entitled to serve extraordinary notice, if the Employee provides inaccurate information in his activity reports or in his travel cost statements.
- (4) Notice will be served in the written form.

Article 11 Medical Examination

The Employee agrees to a medical examination upon recruitment. The costs thus incurred will be borne by the Company.

Article 12 Police Clearance Certificate

Recruitment will require a *Führungszeugnis* [police clearance certificate]. The costs thus incurred will be borne by the Company.

Article 13

Personal data of the employee will be electronically saved.

Article 14 Concluding Provisions

- (1) The present Employment Contract embodies the full agreement between the Parties. The Parties agree that any written or verbal agreements prior to the present Employment Contract will be replaced by the present Contract and will no longer be legally operative.

- (2) Amendments or additions to the present Employment Contract will be subject to the written form to be legally operative.
- (3) Should any one provision of the present Employment Contract be or become legally invalid, the legal validity of the remaining provisions will not be affected hereby. The Parties undertake to replace the legally invalid provisions by those which come as close as possible to the business-related purpose of said provisions.

Limburg/Lahn 29 November 1996

Mundipharma GmbH

Walter Wimmer
Manager

Christof Spitzley



JANUARY 21, 2003

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ROBERT J. PARADISO
485 SEVENTH AVENUE
14TH FLOOR
NEW YORK, NY 10018

Chief Information Officer
Washington, DC 20231
www.uspto.gov

PTAS

JAN 21 2003

DAVIDSON, DAVIDSON & KAPPEL



102248560A

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 10/08/2002

REEL/FRAME: 013368/0776
NUMBER OF PAGES: 3

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:

SACKLER, RICHARD

DOC DATE: 09/25/2002

ASSIGNEE:

EURO-CELTIQUE S.A.
122 BOULEVARD DE LA PETRUSSE
L-2300
LUXEMBOURG, LUXEMBOURG

SERIAL NUMBER: 10214409
PATENT NUMBER:

FILING DATE: 08/06/2002
ISSUE DATE:

SHAREILL COLES, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

10-15-2002

cket No.: 200.1150

FORM PTO-1595 (Modified)
(Rev. 11-01)
OMB No. 0851-0027 (exp. 5/31/2002)
P08A/REV03



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Patent and Trademark Office

102248560

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To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

Richard SACKLER

10-8-02

Additional names(s) of conveying party(ies)

☐ Yes ☒ No

3. Nature of conveyance:

☒ Assignment☐ Merger☐ Security Agreement☐ Change of Name☐ Other

Execution Date: 09/25/02

2. Name and address of receiving party(ies):

Name: Euro-Celtique S.A.

Address: 122 Boulevard de la Petrusse

L-2300

City: Luxembourg

State/Prov.:

Country: Luxembourg

ZIP:

Additional name(s) & address(es)

☐ Yes ☒ No

4. Application number(s) or patent numbers(s):

If this document is being filed together with a new application, the execution date of the application is:

Patent Application No.

Filing date

B. Patent No.(s)

10/214,409

August 6, 2002

Additional numbers

☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Davidson, Davidson & Kappel, LLC

Registration No.

Address: 485 Seventh Avenue

14th Floor

10/15/2002 DATED 00000009 10214409

01 FC:581

40.00 DP

City: New York

State/Prov.: NY

Country: United States

ZIP: 10018

6. Total number of applications and patents involved

1

7. Total fee (37 CFR 3.41):.....\$ 40.00

☒ Enclosed - Any excess or insufficiency should be credited or debited to deposit account☐ Authorized to be charged to deposit account

8. Deposit account number:

50-0552

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9. Statement and signature.

To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Robert J. Paradiso, Reg. No. 41,240

Name of Person Signing

Signature

October 2, 2002

Date

Total number of pages including cover sheet, attachments, and

3

Mail documents to be recorded with required cover sheet information to:
Commissioner of Patents & Trademarks, Box Assignments
Washington, D.C. 20231

ASSIGNMENT

WHEREAS, I (We), Richard SACKLER, residing at 25 Windrose Way, Newtown, Connecticut 06482; respectively, ASSIGNOR(S), have invented certain new and useful improvements in **PHARMACEUTICAL FORMULATION CONTAINING OPIOID AGONIST, OPIOID ANTAGONIST AND IRRITANT**, an application for a Patent of the United States for which:

— I (we) am (are) about to execute;
— was executed on _____ (date(s));
X is identified by Davidson, Davidson & Kappel, LLC, Docket No. 200.1150;
X was filed on August 6, 2002 Serial No. 10/214,409
— I (we) hereby authorize and request our attorney, Davidson, Davidson & Kappel, LLC of 485 Seventh Avenue, 14th Floor, New York, New York 10018 to insert here in parentheses (Application number _____, filed _____) the filing date and application number of said application when known; and

WHEREAS, Euro-Celtique S.A., of Luxembourg, Luxembourg, ASSIGNEE, is desirous of obtaining the entire right, title and interest in, to and under the said invention and the said application:

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to me (us) in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, I (we), the said ASSIGNOR(S), have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over, unto the said ASSIGNEE, its successors, legal representatives and assigns, the entire right, title and interest in, to and under the said invention, and the said United States application and all divisions, renewals and continuations thereof, and all Patents of the United States which may be granted thereon and all reissues and extensions thereof; and all applications for industrial property protection, including, without limitation, all applications for patents, utility models, and designs which may hereafter be filed for said invention in any country or countries foreign to the United States, together with the right to file such applications and the right to claim for the same the priority rights derived from said United States application under the Patent Laws of the United States, the International Convention for the Protection of Industrial Property, or any other international agreement or the domestic laws of the country in which any such application is filed, as may be applicable; and all forms of industrial property protection, including, without limitation, patents, utility models, inventors' certificates and designs which may be granted for said invention in any country or countries foreign to the United States and all extensions, renewals and reissues thereof; and

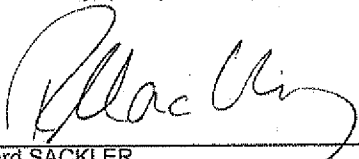
I (WE) HEREBY authorize and request the Commissioner of Patents and Trademarks of the United States, and any Official of any country or countries foreign to the United States, whose duty it is to issue patents or other evidence or forms of industrial property protection on applications as aforesaid, to issue the same to the said ASSIGNEE, its successors, legal representatives and assigns, in accordance with the terms of this instrument; and

I (WE) HEREBY covenant and agree that I (we) have full right to convey the entire interest herein assigned, and that I (we) have not executed, and will not execute, any agreement in conflict herewith; and

I (WE) HEREBY further covenant and agree that I (we) will communicate to the said ASSIGNEE, its successors, legal representatives and assigns, any facts known to me (us) respecting said invention, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing, reissue and foreign applications, make all rightful oaths, and generally do everything possible to aid the said ASSIGNEE, its successors, legal representatives and assigns, to obtain and enforce proper protection for said invention in all countries.

IN TESTIMONY WHEREOF, I (we) hereunto set my (our) hand(s) and seal(s) the day and year set opposite my (our) signature(s).

Dated: 09.25., 2002


Richard SACKLER

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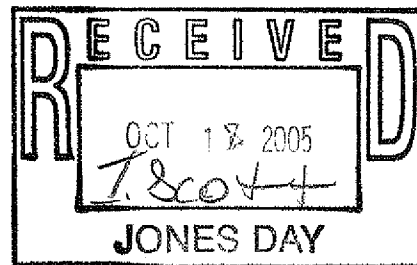
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222 EAST 41ST STREET
NEW YORK, NEW YORK 10017

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RECORDATION DATE: 08/18/2005

REEL/FRAME: 016648/0667
NUMBER OF PAGES: 2

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).
DOCKET NUMBER: 6750-309-999305158-999300

ASSIGNOR:

BROGMAN, BRIANCA

DOC DATE: 11/15/2004

ASSIGNOR:

MUHLAU, SILKE

DOC DATE: 11/12/2004

ASSIGNOR:

SPITZLEY, CHRISTOF

DOC DATE: 11/26/2004

ASSIGNEE:

EURO-CELTIQUE, S.A.
122 BOULEVARD
DE LA PETRUSSE,, LUXEMBOURG L-2330

016648/0667 PAGE 2

SERIAL NUMBER: 10510673

FILING DATE: 05/23/2005

PATENT NUMBER:

ISSUE DATE:

TITLE: MATRIX FOR SUSTAINED, INVARIANT AND INDEPENDENT RELEASE OF ACTIVE
COMPOUNDS

JOANN STEWART, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

18 Aug 05 15:23

212 35-7306 USPTO: 10510673 Des Patent & Remark Office


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Attorney Docket Number
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1. Name of conveying party(ies): Briana Brögmán, Silke Mühlau, Christof Spitzley Additional name(s) of conveying party(ies) attached? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		2. Name and address of receiving party(ies): Name: <u>Euro-Celtique S.A.</u> Address: <u>122 Boulevard de la Petrusse</u> <u>L-2330</u> Country (if other than USA): <u>Luxembourg</u> Zip Code: Additional name(s) & address(es) attached? <input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Nature of conveyance: <input checked="" type="checkbox"/> Assignment Merger Security Agreement Change of Name Other Execution Date: <u>November 15, 2004, November 12, 2004 and November 26, 2004, respectively</u>			
4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date of the application is: A. Patent Application No.(s) <u>10510.673</u> B. Patent No.(s) Additional numbers attached? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
5. Name and address of party to whom correspondence concerning document should be mailed: JONES DAY 222 East 41st Street New York, New York 10017		6. Number of applications and patents involved: <u>1</u> 7. Total fee (37 CFR 3.41):\$ 40.00 Please charge to the deposit account listed in Section 8. 8. Deposit account number: <u>50-3013</u>	
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9. Statement and signature. <i>To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.</i> James G. Markay 31.636  August 18, 2005 Name of Person Signing Reg. No. Signature Date Total number of pages including cover sheet: <u>2</u>			

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CH \$40.00 503013 10510673

JOINT

Pfluggasse 14, 88400 Biberach
 Germany

ASSIGNMENT

WHEREAS, WE, (i) Bianca BRÖGMANN, a citizen of Germany, residing at Hinter dem Brot 4, Ulm, Germany 89073; (ii) Silke MÜHLAU, a citizen of Germany, residing at ~~Baselring 19, Diez, Germany 65582~~ ^{Am Linsengraben 2, 65627 Eltetal-Heuchelheim, Germany}; and (iii) Christof SPITZLEY, a citizen of Germany, residing at ~~Ringstrasse 7a, Elbtal-Heuchelheim, Germany 65627~~ ^{Am Linsengraben 2, 65627 Eltetal-Heuchelheim, Germany} ASSIGNORS, are the inventors of the invention in **MATRIX FOR SUSTAINED, INVARIANT AND INDEPENDENT RELEASE OF ACTIVE COMPOUNDS** for which we have executed an application for a Patent of the United States

- ☒ which is executed on ☐ even date herewith or ☒ November 15, 2004; November 12, 2004 and November 26, 2004, respectively
- ☒ which is identified by Jones Day docket no. 305158-999300
- ☒ which was filed on October 5, 2004, as Application No. 10/510,673, a national stage application of International Application No. PCT/EP03/03541, with an international filing date of April 4, 2003.

and WHEREAS, Euro-Celtique S.A., Assignee, having a place of business at 122 Boulevard de la Petrusse, L-2330 Luxembourg, is desirous of obtaining our entire right, title and interest in, to and under the said invention and the said application:

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to us in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, we, the said ASSIGNORS, have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over, unto the said ASSIGNEE, its successors, legal representatives and assigns, our entire right, title and interest in, to and under the said invention, and the said United States application and all divisions, renewals and continuations thereof, and all Patents of the United States which may be granted thereon and all reissues and extensions thereof; and all applications for industrial property protection, including, without limitation, all applications for patents, utility models, and designs which may hereafter be filed for said invention in any country or countries foreign to the United States, together with the right to file such applications and the right to claim for the same the priority rights derived from said United States application under the Patent Laws of the United States, the International Convention for the Protection of Industrial Property, or any other international agreement or the domestic laws of the country in which any such application is filed, as may be applicable; and all forms of industrial property protection, including, without limitation, patents, utility models, inventors' certificates and designs which may be granted for said invention in any country or countries foreign to the United States and all extensions, renewals and reissues thereof;

AND WE HEREBY authorize and request the Commissioner for Patents and any Official of any country or countries foreign to the United States, whose duty it is to issue patents or other evidence or forms of industrial property protection on applications as aforesaid, to issue the same to the said ASSIGNEE, its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND WE HEREBY covenant and agree that we have full right to convey the entire interest herein assigned, and that we have not executed, and will not execute, any agreement in conflict herewith.

AND WE HEREBY further covenant and agree that we will communicate to the said ASSIGNEE, its successors, legal representatives and assigns, any facts known to us respecting said invention, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing, reissue and foreign applications, make all rightful oaths, and generally do everything possible to aid the said ASSIGNEE, its successors, legal representatives and assigns, to obtain and enforce proper protection for said invention in all countries.

IN TESTIMONY WHEREOF, We hereunto set our hands and seals the day and year set opposite our respective signatures.

Date August, 1st, 2005

Bianca Brögmann L.S.
 Bianca BRÖGMANN

WITNESS: Gertud Thedinga
GERTRUD THEDINGA

(Printed Name)

Date Aug. 05, 2005

Silke Mühlau L.S.
 Silke MÜHLAU

WITNESS:

R. Ziegler
 (Printed Name) REGINA ZIEGLER

Date 06 / 29, 2005

Christof Spitzley L.S.
 Christof SPITZLEY

WITNESS:

C. Stein
 (Printed Name) Claudia Stein